

to Claims 1, 3-11 and 13-21, Applicant respectfully submits that these are not obvious in light of the cited reference.

Claim 1, upon which Claims 3-11 and 13 depend, has been amended to incorporate the frequency range previously set forth in Claim 12. That range, "between approximately 400 and 800 Herz," makes clear that the acoustic waves are within an audible sound range. Independent Claim 14, upon which Claims 15-20 depend, also claims the provision of audible acoustic waves; i.e., waves having a frequency of about 600 Herz. This is not disclosed in Weth.

In the Office Action, the Examiner stated that reference number 9 in Weth was a sonic transducer. Weth identifies reference number 9 as an "ultrasound applicator." However, ultrasound waves are any sound wave with a frequency above 20,000 Herz, and are inaudible. Nowhere in Weth is the transmission of audible sound waves taught, and indeed, an ultrasound applicator does not transmit such waves. Accordingly, the ultrasound applicator of Weth does not transmit audible, acoustic waves, as claimed herein.

Applicant further submits that the placement of the container away from the person to be treated cannot be considered obvious in light of Weth, given that Weth teaches away from such positioning. Thus, a review of the Weth references shows that it is directed to a variant on Atlas therapy, which Weth describes as "the therapy of pains in the spinal column region [that] is enabled by manual pulses (manipulation), particular striking with fingers onto one of the transverse processes of the first neck vertebra." Col. 1, lines 47-50. However, according to Weth, because Atlas therapy

must be "manually implemented," it "cannot be reproduced." Col. i, lines 65-67. Weth seeks to solve this problem through automation of wave production, so that "the energy content and temporal curve of the pulse-like wave can be reliably reproduced." Col. 2, lines 14-15.

Thus, it can be seen that Weth only teaches an Atlas-type therapy, in which the pulse-like wave is conducted directly onto the body of the patient. There is no teaching or suggestion in Weth that it might be possible, or beneficial, to position a wave source away from the person to be treated. Accordingly, Applicant respectfully submits that the feature of Claims 1 and 14 that the person be positioned between "one foot and approximately twenty feet" from the container -- i.e., not in physical contact with the container -- is not obvious in light of Weth.

With specific regard to Claim 21, Applicant notes that Claim 21 includes the step of positioning at least a portion of the body of a person "in" the liquid and transducer containing container. The container (1) of Weth is disclosed as being positioned outside the body of the person being treated, consistent with the teaching of that reference that it is a form of Atlas therapy. There is no disclosure in Weth of a container having sufficient dimension to be able to receive a portion of the body of a person therein for treatment, much less that such a treatment would be beneficial. Accordingly, Applicant respectfully submits that Claim 21 is not obvious in light of Weth.

II. Rejections Based on 35 U.S.C. § 112(1) and 35 U.S.C. § 101

In the Office Action, the Examiner rejected Claims 1 and 3-21 previously on file based on 35 U.S.C. 112, first paragraph, and based on 35 U.S.C. 101. According to the Examiner, "[I]t is unclear how someone who is suffering from inflammatory musculoskeletal connective disorder can be treated by acoustic waves at a distance of between 1 to 20 feet, no matter how long the treatment may occur." The Examiner further asserts that the disclosed invention "is inoperative and therefore lacks utility."

In response to these rejections, Applicant notes that testing of the method claimed herein has been underway under the auspices of the University of Nevada Las Vegas. Specifically, the claimed method has been tested on patients suffering from osteoarthritis, a type of body tissue disease, and also on patients suffering from peripheral vascular disease ("PVD"), a type of circulatory disorder. Each study has resulted in an article that has been submitted for publication in a peer-reviewed medical journal. Copies of these articles are attached as Exhibits A and B to the declaration of inventor Alphonse Cassone, submitted herewith.

With specific regard to osteoarthritis, all of the twenty-one test participants demonstrated significant improvement both in range of motion and in pain reduction. See "Effects of a Low Frequency Sonic Waveform on Osteoarthritis: A Pilot Study," pp. 7-8, attached as Exhibit A to Cassone Declaration submitted herewith. According to the Osteoarthritis article:

All of the participants in this study showed improvement

over a 24-hour period. We also demonstrated that exposure to the sonic waves at the designated frequency significantly increased the ROM in several of the body areas examined immediately post treatment as well as 24 hours post treatment. Additionally, the intervention significantly decreased pain immediately post treatment and 24-hours post treatment. No untoward side effects were noted.

Id. at p. 8. The osteoarthritis study concludes by stating that "the results of this pilot study suggest that use of the Cassone transducer as an alternative form of therapy appears to improve ROM while decreasing pain." Id. at p. 9.

With respect to the PVD study, thirteen of the fifteen participants also benefited from the treatment, including increased blood flow and pain alleviation. See "The Effects of a Low Frequency Sonic Waveform on Peripheral Vascular Disease: A Pilot Study," Summary, p. 8, Exhibit B to Cassone Declaration submitted herewith.

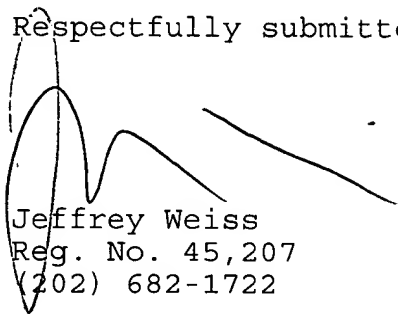
Applicant respectfully submits that the results of these studies, as documented in the articles submitted herewith, establishes both enablement and utility of the claimed invention. Moreover, with specific regard to the Section 112 rejection, Applicant notes the well-established rule "that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests." Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565 (Fed. Cir. 1983). Nevertheless, the

osteoarthritis article submitted herewith states that: "Audible sound has been shown to have physiological effects on the body and its metabolic processes by activating subcortical neural systems. By activating these systems, the cardiovascular, metabolic, endocrine, reproductive, and neurological functions of the body may be altered." "Effects of a Low Frequency Sonic Waveform on Osteoarthritis: A Pilot Study," p. 3, attached as Exhibit A to Cassone Declaration submitted herewith. This represents a possible explanation for the beneficial effects shown from treatment of patients with the claimed invention.

Applicant respectfully submits that Applicant's Claimed Invention is deserving of patent protection because it describes a useful and functional method which patentably distinguishes over the cited prior art. In conclusion, Applicant respectfully submits that this Amendment, including the amendments to the Claims and in view of the Remarks offered in conjunction therewith, are fully responsive to all aspects of the objections and rejections tendered by the Examiner in the Office Action. Applicant respectfully submits that he has persuasively demonstrated that the above-identified Patent Application, including Claims 1, 3-11, and 13-20 is in condition for allowance. Such action is earnestly solicited.

If there are any fees incurred by this Amendment Letter,
please deduct them from our Deposit Account No. 23-0830.

Respectfully submitted,



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Claim Amendments - Version With Markings to Show Changes Made

Claim 1 (Twice Amended) A method for treating inflammatory musculoskeletal connective tissue disorders comprising the steps of:

providing a low frequency sonic transducer;

immersing said low frequency sonic transducer in a liquid-containing container;

positioning a person having an inflammatory musculoskeletal connective tissue disorder a therapeutically beneficial distance from said container;

wherein said therapeutically beneficial distance is between approximately one foot and approximately twenty feet from said container; and

exposing said person for a therapeutically beneficial period of time to acoustic waves from said low frequency sonic transducer at a therapeutically beneficial frequency;

wherein said therapeutically beneficial frequency is between approximately four hundred and eight hundred Hertz.